K960373

BIOJECT

January 24, 1996

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BIOJECT INC.
7620 S.W. BRIDGEPORT ROAD
PORTLAND, OREGON 97224
TELEPHONE: (503) 639-7221
FAX: (503) 624-9002

510(k) SUMMARY (21CFR Subpart 807.92)

(a)(1) Submitter Identification:

Bioject, Inc.
7620 SW Bridgeport Road
Portland, OR 97224
800-683-7221
503-624-9002 (fax)

Contact Person:
Mary K. Norton
Manager, Regulatory Affairs/Quality Assurance

(a)(2) Device Name: Biojector® 2000 Needle-Free Injection Management System™
Common Name: Needleless Injector, Jet Injector
Classification Name: Non-electrically Powered Fluid Injector, 21 CFR 880.5430

(a)(3) Predicate Device: Biojector® 2000 Jet Injection System (K920631)

(a)(4) Device Description: The Biojector® 2000 is a needle free injection management system designed to deliver drugs both subcutaneously (SC) and intramuscularly (IM). It is a non-electrically powered device which is intended to administer an injection by means of a high velocity jet of fluid that penetrates the surface of the skin and delivers drug to the body. The system is comprised of three major components: The single use sterile medication syringe (medication container), the Biojector® (injector), and the Carbon Dioxide (CO_2) cartridge (power source). The device is also capable of being powered with a CO_2 tank with a specialized adapter.

The syringe holds a variable volume of drug up to a maximum of one cubic centimeter (cc) or milliliter (ml.). Volume increments are marked at 0.10, 0.20, 0.25, 0.30, 0.40, 0.50, 0.60, 0.75, 0.80, 0.90, and 1.0 cc or ml. The syringe is filled using either a fill needle, or a plastic fluid transfer device. Once the syringe is filled, it is loaded in the Biojector®. Syringes are available in five sizes which are numbered 2, 3, 4, 5 and 7. The syringe sizes have the following orifice diameters: 0.004, 0.006, 0.008, 0.010 & 0.014 inches, respectively. The number 2 syringe is used for all subcutaneous injections. The remaining syringes, numbered 3, 4, 5, and 7, are used for intramuscular injections. Depth of penetration of the drug varies with the orifice diameter selected. The larger the orifice diameter, the deeper the penetration of the drug.

Activation of the Biojector® is initiated when the actuator is depressed. CO2 gas is released, through the action of a series of valves within the injector. This causes the plunger to push the drug out of the sterile syringe, through the syringe orifice at a high velocity, allowing it to penetrate the skin and be deposited in the tissue. Exhaust CO2 is expelled, through the exhaust and bleed valves, in the rear section of the Biojector®, as well as into the cartridge compartment. The CO2 does not come in contact with the drug.

(a)(5) Intended Use: The Biojector® 2000 Needle-Free Injection Management System™ which is the subject of this submission and the currently marketed (predicate) Biojector® 2000 Jet Injection System (with tank adapter), K920631, are intended to deliver subcutaneous (SC) or intramuscular (IM) injections of vaccines and other injectable medications. Both the Biojector® 2000 (subject of submission) and the predicate device may be used by physicians, nurses, veterinarians, and podiatrists and other practitioners who routinely administer injections. The Biojector® 2000 (subject of submission) may also be used by patients authorized by their physicians to self inject at home, or have other individuals administer injections of prescribed drug. It should be noted that a prior submission made by Bioject (K861687), predicate to K920631, was cleared via the 510(k) process for professional and home use.

(a)(6) This Premarket Notification describes modifications to the Biojector® 2000 device previously described via the 510(k) process (K920631). A summary of these modifications includes:

- Changing from a two piece to a one piece main body design with related minor design changes to ease manufacturing;
- Incorporation of design modifications to the exhaust and bleed valves to improve CO2 efficiency and performance;
- Changes in material involved replacing metal parts with plastic parts for cost reduction purposes and to add alternate vendors for existing materials;
- Labeling revisions including the addition of a Home Use Instruction Manual.

There are no changes in intended use or operational principle. Substantial equivalence is based upon equivalence in intended use, labeling, design, materials and operational principle to the Biojector® Jet Injection System (with tank adapter), K920631 and there are no new safety and efficacy issues as a result of the design modifications.

Product qualification testing and biocompatibility data for the modified device (subject of submission) and the current, predicate device (K920631), demonstrate the new model to be functionally equivalent to the predicate device. The device is as safe and effective as the legally marketed, predicate device, and does not raise questions of safety and efficacy different than that of the predicate.